REMARKS

Claims 7 to 10, 15, 18, and 19 are now pending in this application. Claim 17 has been canceled. Claim 15 has been amended and claims 18 and 19 have been added. Support for the amendment and new claim can be found throughout the specification, particularly at page 3, lines 15 to 17, page 7, lines 2 to 10 and lines 14 to 15, page 8, line 19, page 9, lines 24 to 25, and at page 16, lines 3 to 7. This amendment and new claims add no new matter to the present application.

Withdrawn Objections and Rejections

Applicants acknowledge the Examiner's withdrawal of the following objections and rejections raised in the Office Action dated March 26, 2002:

a) objection to claim 7;

b) rejection of claims 7 and 9 under 35 U.S.C. § 102(b) as allegedly anticipated by Svenson et al. (*J. Immun. Methods* 25(40):323-335 (1979));

c) rejection of claim 7 and 9 under 35 U.S.C. § 102(b) as allegedly anticipated by Kamath et al. (*Glycoconjugate Journal*, 13:315-319 (1996)); and

d) rejection of claims 7 to 10, 15, and 17 under 35 U.S.C. § 103 as allegedly obvious over McDonald et al. (U.S. Patent No. 5,716,793) in view of Semprevivo (*Carbohydrate Research*, 177:222-227).

However, applicants respectfully submit that all of the pending claims are in condition for allowance for the reasons discussed below.

35 U.S.C. § 102

Claim 15 remains rejected as allegedly anticipated by Stuart et al. (*Immunology*, 68:469-473 (1989)) because, according to the Office Action (at page 4):

> There is nothing on the record to show that the purified chlamydial glycolipid exoantigen of the prior is different from the claimed purified chlamydial glycolipid exoantigen.

Applicants respectfully traverse this rejection for the following reasons.

In the interest of moving this application toward allowance, applicants have amended claim 15 to recite a purified preparation of chlamydial glycolipid exoantigen (GLXA). Amended claim 15 clearly indicates that applicants claim a preparation of GLXA that is, as a whole, free of other components as determined by sodium dodecylsulfate polyacrylamide gel electrophoresis (SDS-PAGE) and silver staining.

Stuart does not disclose preparations of GLXA that are free of other components. Rather, the preparations described in Stuart include GLXA and a mixture of other materials. As discussed in applicants' response to the previous Office Action, these contaminating materials were visualized in Stuart using sodium dodecylsulfate polyacrylamide gel electrophoresis (SDS-PAGE) and silver staining (see, e.g., Stuart at Figs. 2 and 5). Stuart acknowledges that the preparations contain additional materials, stating (at page 472, right column, lines 28 to 35):

> The SDS-PAGE analyses also indicate that a variety of molecular weight species exist and are detectable, with bands also occurring at 43,000 MW and 30,000 MW. This overall pattern is consistent with different serovars and appears to be identical whether the GLXA is isolated by monoclonal antibody affinity chromatography or dissociation of polyclonal antibody-antigen complexes isolated by molecular shift chromatography.

The preparations taught by the present application and recited in claim 15, on the other hand, are purified and free of other components (see the specification at page 2, lines 21 to 25; quoted below).

Further, to provide a clear record, applicants wish to correct a sentence in the Office Action that, as presently written, misquotes applicants' specification. At page 3, the Office Action states (emphasis added):

> It should be noted that Applicant's specification discloses that "purified chlamydial glycolipid exoantigen wherein the purified chlamydial glycolipid exoantigen that is free of other components as determined by sodium dodecylsulfate gel electrophoreses and silver staining *was prepared according to the teachings of* Stuart et al, (Immunology, 1989, 68, p. 469-473)" (page 2).

However, applicants' specification actually states (at page 2; emphasis added):

> The invention also includes a purified GLXA, where the purified GLXA is free of other components as determined by sodium dodecylsulfate gel electrophoreses (SDS-PAGE) and silver staining, using the methods described in Stuart et al.,

> Immunology 68:469-473, 1989. To distinguish whether a band on a SDS-PAGE gel is GLXA, the bands can be transferred to a membrane and visualized as a Western blot using GLXA-specific antibodies. *The purified GLXA can be produced by the methods of purifying GLXA described herein.*

The above-quoted language of the Office Action appears to suggest that applicants' specification states that the purified preparations described and claimed in the present specification were produced using the methods described in Stuart. This is not true. Rather, the specification indicates that purified GLXA can be determined to be free of other components using SDS-PAGE and silver staining methods described in Stuart. The specification clearly states that purified GLXA can be produced by the methods described in the specification. This is an important distinction because the methods described in the specification differ from those described in Stuart, e.g., in the antibodies used for GLXA purification (see, e.g., the specification at page 15, lines 15 to 17).

Based on the above and the data published in Stuart, it is clear that Stuart does not disclose a purified preparation of GLXA that is free of other components. Because Stuart does not disclose all of the elements of claim 15, Stuart does not anticipate the present claim. Thus, applicants respectfully request that the present rejection be reconsidered and withdrawn.

Claims 7 to 9 and 17 were rejected as allegedly anticipated by McDonald et al. (U.S. Patent No. 5,716,793). Claim 17 has been canceled without prejudice, rendering the present rejection moot with respect to this claim. With respect to claims 7 and 9, applicants respectfully disagree with this rejection for the following reasons.

The Office Action states (at page 4):

> MacDonald et al teach a covalently bound immune complex comprising paramagnetic particles (i.e. carrier group), GLXA, GLXA-antibody and GLXA-antibody labeled monoclonal GLXA-antibody IgG) (column 14, lines 34-40). The linker used to couple the carrier group to the oligosaccharide would be inherent in the teachings of the prior art.

As a threshold issue, applicants submit that the pending claims recite compositions that include discrete oligosaccharide(s), not whole GLXA including such an oligosaccharide(s). The language used in the claims clearly specify this characteristic of the oligosaccharide(s). For

example, as the Office Action acknowledges (at page 4), claims 7 to 9 recite compositions that include a carrier group coupled to an oligosaccharide obtained from a chlamydial glycolipid. The meaning of "obtained from" is made clear throughout the specification, e.g., at page 7, lines 1 to 10, which state (emphasis added):

> To produce an antigen useful in a therapeutic or prophylactic composition, such as a chlamydia vaccine, oligosaccharides can be released from an isolated glycolipid. This can be done using, e.g., standard mild acid hydrolysis or glycosidase treatment.
>
> * * *
>
> These oligosaccharides can include non-reducing end groups, repeating subunits, and/or core portions of the glycolipid. *In addition*, the oligosaccharides *obtained from* a particular glycolipid are expected to contain the same carbohydrate residues as in the glycolipid itself.

Based on the above, any skilled practitioner would recognize that the claims recite compositions that include isolated oligosaccharide(s) having the same carbohydrate residues as oligosaccharides naturally associated with whole GLXA.

New claim 18 recites a composition comprising a carrier group coupled to an isolated oligosaccharide capable of binding anti-GLXA monoclonal antibody 89MS30. Applicants submit that claim 18 also indicates clearly that the recited composition includes a discrete oligosaccharide that is not a part of whole GLXA.

New claim 19 depends from claim 7 and recites that the carrier group is selected from bovine serum albumin (BSA), tetanus toxoid, Diphtheria CRM197 Protein (CRM 197), ovalbumin, and an organic polymer. None of these materials is described in McDonald as a carrier group that can be coupled to an oligosaccharide obtained from a chlamydial glycolipid.

McDonald, on the other hand, describes methods for detecting chlamydia in biological samples. Specifically, the methods described in McDonald involve contacting biological samples with GLXA-Ab_1 or – Ab_3 to detect GLXA in a biological sample. The immune complex in McDonald (column 14, lines 34 to 40) to which the Office Action refers includes whole GLXA, not a discrete oligosaccharide. McDonald does not disclose compositions that include a carrier group coupled to discrete oligosaccharides having the same carbohydrate residues as those that are naturally associated with GLXA. Further, McDonald does not disclose using any of the materials recited in new claim 19 as carrier groups.

Because McDonald does not disclose all of the elements of claims 7 to 9, 18, and 19, McDonald does not anticipate these claims. Thus, applicants respectfully request that the present rejection be reconsidered and withdrawn.

35 U.S.C. § 103

Claims 7 to 10 and 17 were rejected as allegedly obvious over McDonald et al. (U.S. Patent No. 5,716,793) in view of Smith et al (*J. Biol. Chem.* 255(1):55-59 (1980)). Claim 17 has been canceled without prejudice, rendering the present rejection moot with respect to this claim. Applicants respectfully traverse this rejection for the reasons discussed below.

In support of the finding of obviousness, the Office Action states (at page 6):

> It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use the β-(p-aminophenyl)ethylamide (i.e. 2-(4-aminophenyl)ethylamine) linkers as taught by Smith et al to covalently bond the carrier group (i.e. paramagnetic particles) to the oligosaccharide of MacDonald et al because Smith et al have demonstrated that β-(p-aminophenyl)ethylamide linkers can be used to form oligosaccharide-protein conjugates (see the abstract).

As discussed above, McDonald describes methods for detecting chlamydia in biological samples, e.g., by contacting biological samples with GLXA-Ab_1 or – Ab_3 to detect GLXA in a sample. McDonald does not disclose isolated oligosacharides obtained from this chlamydial glycolipid. McDonald does not even suggest that useful individual oligosaccharides should be (or could be) cleaved from GLXA, or chemically synthesized based upon these oligosaccharides. Accordingly, McDonald does not disclose or suggest that such isolated oligosaccharide(s) could be coupled to a carrier, nor does it suggest methods for performing such coupling.

The Office Action also cites Smith. However, Smith does not provide the information missing in McDonald. Smith describes a method for derivatizing free oligosaccharides from human milk for coupling to proteins, and the use of such oligosaccharide-protein conjugates to generate immune responses in rabbits. Smith does not disclose chlamydial glycolipids such as GLXA. Further, Smith does not even suggest that Smith's methods could have been utilized with whole glycolipids from prokaryotes of the genus *Chlamydia*, or for that matter, any other prokaryotic organism.

Applicants submit that a person skilled in the art would not have been motivated by Smith to modify the methods described in McDonald to create the compositions recited in claims 7 to 10 (and new claims 18 and 19). Neither publication suggests that useful oligosaccharides could, or should have been isolated from chlamydial glycolipids such as GLXA, or that they could have been coupled to carriers using the methods taught in the present application.

Further, even if the GLXA described in McDonald were treated using the method and linker described in Smith, the compositions of claims 7 to 10, 18, and 19 would not have been obtained. This is the case, in part, because GLXA and other commonly occurring glycolipids do not, as part of the native molecule, contain reducing ketone or aldehyde groups. Thus, to prepare a GLXA component for derivatization, it must first be subjected to trifluoroacetolysis to develop such a group(s) (see, e.g., the specification at page 15, line 28, to page 16, line 2). Smith does not disclose, or even suggest, treating glycolipids using trifluoracetolysis to develop such groups. Therefore, even if the methods described in Smith were used to treat GLXA, applicants' claimed compositions would not have been obtained.

Applicants submit that neither of the publications cited in the Office Action, singly or in combination, suggest developing the compositions of the present invention. Therefore, applicants respectfully request that this rejection be reconsidered and withdrawn.

CONCLUSION

Applicants submit that all claims are in condition for allowance, which action is requested. Attached is a marked-up version of the changes being made by the current amendment. The mark-up version is entitled "Version with Markings to Show Changes Made." No fees are believed to be due. However, please apply any charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket Number 08952-008001.

Respectfully submitted,

Date: 03-03-03

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Version with Markings to Show Changes Made

In the Claims:

Claim 17 has been canceled.

Claims 18 and 19 have been added.

Claim 15 has been amended as follows:

15. A purified preparation of chlamydial glycolipid exoantigen, wherein the preparation [purified chlamydial glycolipid exoantigen] is free of other components as determined by sodium dodecylsulfate gel electrophoreses and silver staining.